REMARKS

The Official Action of October 14, 2008, has been carefully reviewed, and in view of the above amendments and the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

In the above Official Action claims 1, 6, 7, 9 and 10 were rejected as being anticipated by Eggers et al. (U.S. Patent No. 6,206,524), claim 11 was rejected as being obvious over Eggers et al., claims 2-3 were rejected as being obvious over Eggers et al. in view of Haim et al. (U.S. Patent No. 6,309,370), claims 12, 13, and 15-17 were rejected as being obvious over *Haim et al.* in view of Eggers et al., claims 4 and 5 were rejected as being obvious over Eggers et al. in view of Shapland et al. (PCT Publication No. WO 99/04851) and claim 14 was rejected as being unpatentable over Haim et al. in view of Eggers et al. and Shapland et al.

As set forth above, independent claims 1, 12 and 15 have been amended to recite, *inter alia*, an "electrode fixed at said distal end portion of said insertion member and spaced from a bevel of said injection needle disposed at said distal end portion of said insertion member for measuring a cardiac action potential." A description of the electrode being fixed to the insertion member is provided in Paragraph [0068] of the present specification.

Referring to FIG. 8B of Eggers et al., upon which the Examiner relies, Eggers et al. disclose an energy applicator 60 including shaft 61 having lumen 62. Distal edge 63 of tubular shaft 61 preferably includes bevel 64 to facilitate introduction and advancement of the energy applicator into biological tissue 120, and includes an exposed region forming distal electrode 65. Energy applicator further includes proximal electrode 66 and insulation layers 67 and 68. The hub and control device

used with energy applicator 60 are modified to allow the introduction and positioning of extraction device 130 (e.g., a biopsy needle) through lumen 62, as shown in FIG. 8B, for example, to permit aspiration of debris from the treatment site through lumen 62. Col. 12, lines 35-48. More particularly, a biopsy needle 130 may be inserted through lumen 62 so that a portion of the tissue protrudes into cavity 131 formed in region 132 of the biopsy needle. When energy applicator 60 is then displaced distally along biopsy needle 130, bevel 64 of shaft 61 severs the tissue, thereby permitting sample of tissue 121 to be withdrawn for pathological examination prior to the initiation of therapeutic cauterization. Col. 12, lines 49-56.

It is apparent from the above disclosure of Eggers et al. that the electrodes 65, 66 are disposed on the tubular shaft 61 of the energy application 60 -- not fixed on the biopsy needle 130. Hence, with this arrangement, it is impossible to detect whether or not the leading edge of the biopsy needle 130 securely punctures the target tissue. In contrast, the claimed invention has an electrode fixed at the distal end portion of the insertion member and spaced from a bevel of the injection needle disposed at the distal end portion of the insertion member.

Haim et al., upon which the Examiner also relies, discloses a catheter 20 comprising a hollow needle 24 within the catheter's distal end 22 for injection of a drug into the myocardium. Referring to FIG. 1A, the needle is shown in a first configuration in which it is retracted into a sheath 26 inside the catheter 20, whereas in FIG. 1B, the needle extends distally out of distal end 22 for injection of the drug. The catheter 20 also comprises one or more contact sensors 36, i.e., pressure sensors, which generate signals responsive to contact between distal end 22 and the heart wall so as to assure proper contact between the catheter and the wall before

extension of needle 24. The catheter 20 may also comprise one or more electrodes 38 which are used to measure electrical activity in the heart wall in order to assess and map the local viability of the heart tissue.

In contrast to independent Claims 1, 12 and 15, the electrodes in Haim et al. are disposed on the distal end of the sheath 26, not on the distal end of the hollow needle or spaced from a bevel of needle 24.

Accordingly, even combining the teaching of Eggers et al. and Haim et al., the cited prior art fails to disclose or suggest that the electrode is fixed at the distal end portion of the insertion member, and spaced from a bevel of the injection needle disposed at the distal end portion of the insertion member, for measuring a cardiac action potential.

For at least the reasons set forth above, Applicants submit that the prior art relied upon by the Examiner do not disclose or suggest an electrode disposed at the distal end portion of the insertion member and spaced from the bevel of the injection needle disposed at the distal end portion of said insertion member for measuring a cardiac action potential.

The dependent claims are allowable at least by virtue of their dependence from allowable independent claims. Thus, a detailed discussion of the additional distinguishing aspects recited in the dependent claims is not set forth at this time.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully submit that the claims of the present application are now in condition for allowance, and an early indication of the same is earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference would be helpful in resolving any remaining issues pertaining to this application; the Examiner is kindly invited to call the undersigned counsel for Applicant regarding the same.

Respectfully submitted,

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Date: July 30, 2009

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